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| Application Number | 10/735,335 |
| Filing Date | December 12, 2003 |
| First Named Inventor | Doddabele L.Madhavi |
| Art Unit | 1623 |
| Examiner Name | Matthew L. Fedowitz |
| Attorney Docket Number | BIO 2-016 |

U. S. PATENT DOCUMENTS

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Signature**

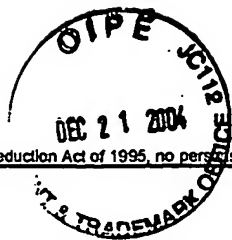
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STATEMENT BY APPLICANT**

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Sheet

2

of

3

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|--------------------|-----------------------|---|----------------|
| | 1. | SKALKO-BASNET, et al., "Influence of Surfactants (Present in the Dissolution Media) on the Release Behaviour of Tolbutamide from its Inclusion Complex with B-Cyclodextrin", Eu | |
| MF | 2. | YU, et al., "Effect of camphor/cyclodextrin complexation on the stability of O/W/O multiple emulsions", Int J Pharm 2003 Aug 11;261(1-2):1-8. | |
| MS | 3. | VALERO, et al., "Ternary naproxen: beta-cyclodextrin:polyethylene glycol complex formation", Int J Pharm 2003 Oct 20; 265(1-2):141-9. | |
| | 4. | VEIGA, et al., "Influence of surfactants (present in the dissolution media) on the release behaviour of tolbutamide from its inclusion complex with beta-cyclodextrin", Eur J. | |
| MF | 5. | TONNESEN, et al., "Studies of curcumin and curcuminoids, XXVII. Cyclodextrin complexation: solubility, chemical and photochemical stability", Int J Pharm. 2002 Sep 5;244(1-2) | |
| | 6. | MURA, et al., "Effects of the host cavity size and the preparation method on the physicochemical properties of ibuprofen-cyclodextrin systems", Drug Dev Ind Pharm. 1999 Mar;25(| |
| | 7. | ALEXANDER, et al., "Chiral discrimination in cyclodextrin complexes of amino acid derivatives: beta-cyclodextrin/N-acetyl-L-phenylalanine and N-acetyl-D-phenylalanine complex | |
| | 8. | VAKILY, et al., "Inclusion complexation of heptakis (2, 6-di-O-ethyl)-beta-cyclodextrin with naprofenic acid: pharmacokinetic consequences of a pH dependent release and stereo | |
| MF | 9. | MURA, et al., "Influence of the Preparation Method on the Physicochemical Properties of Binary Systems of Econazole with Cyclodextrins", Int Journ of Pharm 193 (1999) 85-95. | |
| | 10. | AHSAN, et al., "Mutual Inhibition of the Insulin Absorption-Enhancing Properties of Dodecylmalloside and Dimethyl-B-Cyclodextrin Following Nasal Administration", Pharm Res V | |

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| Sheet 3 | of 3 | Attorney Docket Number | BIO 2-016 |

| NON PATENT LITERATURE DOCUMENTS | | | |
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| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| MF | 11. | LOCKWOOD, et al., "Improved Aqueous Solubility of Crystalline Astaxanthin (3,3'-dihydroxy-B, B-carotene - 4,4'-dione) by Captisol (Sulfobutyl Ether B-Cyclodextrin)", Jour of Pharm Sci, Vol 92, 922-926 (2003). | |
| | 12. | SPIRICHEV, et al., "[Study of bioavailability of different forms of synthetic beta-carotene in volunteers]", Vop Pitan. 1996(6) :22-6. Article in Russian. | |
| MF | 13. | MIYAKE, et al., "Improvement of solubility and oral bioavailability of rutin by complexation with 2-hydroxypropyl-beta-cyclodextrin", Pharm Dev technol 2000;5(3) :399-407. | |
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